

COMPLETE LISTING OF CLAIMS INCLUDING AMENDMENTS

1. **(currently amended)** A device comprising:
an elongate body comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a lumen in the elongate body, said lumen extending between the proximal and distal ends; and
a diffuser element operatively associated with the elongate body so as to define a diffusion space, wherein the elongate body distal end outlet is disposed in and in fluid communication with the diffusion space, and wherein the diffuser element is drug-permeable and water-permeable to provide for dilution of a drug in the diffusion space, and the diffuser element is substantially impermeable to biological fluids or components of biological fluids.
2. **(previously amended)** The device of claim 1, wherein the diffuser element comprises a semipermeable membrane, a microporous membrane or an ion exchange membrane.
3. **(canceled)**
4. **(previously amended)** The device of claim 1, wherein the distal outlet of the elongate body is defined by an exit orifice of a drug delivery device and the diffuser element is a cap in which the exit orifice is disposed.
5. **(canceled)**
6. **(original)** The device of claim 1, wherein the diffusion space is defined by an outer wall of the elongate body and an inner wall of the diffuser element.

7. **(previously amended)** The device of claim 1, wherein said diffuser element surrounds at least a portion of said elongate body.

8. **(original)** The device of claim 1, wherein the diffuser element is microporous.

9. **(original)** The device of claim 1, wherein the diffuser element is a dense membrane.

10. **(original)** The device of claim 1, wherein the diffuser element is an ion-exchange membrane.

11. **(previously amended)** The device of claim 1, wherein a diffuser element distal end extends distally beyond the elongate body distal end.

12. **(previously amended)** The device of claim 1, wherein the diffuser element is a ring-shaped element.

13. **(previously amended)** The device of claim 1, wherein the diffuser element is selectively permeable to water.

14-18. **(canceled)**

19. **(previously amended)** The device of claim 1, wherein the elongate body lumen is adapted for delivery of agent at a low volume rate.

20. **(previously amended)** A drug delivery system comprising the device of claim 1 operably attached to a drug reservoir.

21. (previously amended) The drug delivery system of claim 20, wherein the drug reservoir contains Baclofen.

22. (previously amended) The drug delivery system of claim 20, wherein said drug is delivered in microliter or submicroliter quantities per day.

23. (canceled)

24. (previously amended) The method of claim 25, wherein the formulation is introduced into the inlet at a low volume rate.

25. (previously amended) A method for delivery of an agent to a delivery site in a subject, the method comprising the steps of:

(a) implanting at the delivery site at least a distal portion of a device, the device comprising:

an elongate body comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a lumen in the elongate body, said lumen extending between the proximal and distal ends; and a diffuser element operatively associated with the elongate body so as to define a diffusion space, wherein the elongate body distal end outlet is disposed in and in fluid communication with the diffusion space, wherein the diffuser element is drug-permeable and water-permeable so as to provide for dilution of a drug in the diffusion space and movement of drug out of the device; and

(b) introducing into the elongate body inlet a drug at a first concentration, wherein said drug moves through the elongate body lumen, out the elongate body outlet,

and into the diffusion space, and further wherein water from the environment outside the device passes into the diffusion space through the diffuser element to dilute drug in the diffusion space to a second concentration, and wherein said diluted drug diffuses out through the diffuser element to exit the device at the delivery site in the subject.

26 - 28. (canceled)

29. (previously presented) The device of claim 1 wherein the diffuser element comprises a polymeric film.

30. (previously amended) The device of claim 29 wherein the diffuser element has a Diffusion Coefficient (DC) value in the range between 4.1×10^{-6} and 3.3×10^{-5} $\mu\text{g}/\text{cm/sec}$.

31. (previously amended) The device of claim 1, wherein the elongate body is drug-impermeable, and further wherein the diffuser element is substantially impermeable to drug and selectively permeable to water.

32. (previously presented) The method of claim 25, wherein the elongate body lumen is at least partially filled with a drug formulation prior to said implanting.

33. (new) The device of claim 1, wherein the diffuser element is substantially impermeable to biological fluids or components of biological fluids.